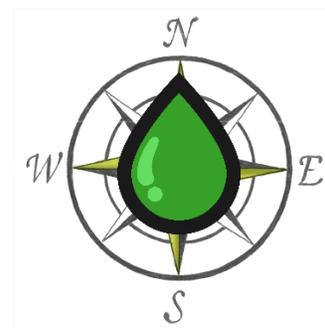


CBD, it's everywhere but is it legal?



By: Allison N. Zsamba

Cannabidiol or CBD is the latest craze. Today, we see CBD products sold everywhere, from our local gas stations, to pharmacies, even at our pet supply stores. Still, many people do not understand what CBD is and whether it is legal to consume, sell or purchase. Weeding through these issues is no easy task.



Foundationally, marijuana and hemp are both cannabis plants. Marijuana commonly refers to cannabis plants that contain high levels of tetrahydrocannabinol (“THC”), a psychoactive compound that produces a high when consumed. Hemp, on the other hand, is considered very environmentally friendly, given how quickly and easily the plant can grow. It also has an almost unlimited number of potential, non-drug related uses, from clothing to paper to cosmetics. As such, the United States has recently radically shifted its cannabis policies in recognition of the substantial benefits of hemp usage under the 2018 Farm Bill, 7 USCS. § 1639o, *et. seq.* Now, in order for a cannabis plant to be legally identified as hemp, it must contain less than 0.3 % THC. Generally, hemp contains high levels of a compound called cannabidiol or CBD, which is non-psychoactive. In fact, the Federal Drug Administration (“FDA”) has approved the CBD drug Epidiolex for use in treating epilepsy conditions.

Specifically, the 2018 Farm Bill changed federal cannabis policy by: (1) removing hemp from the definition of marijuana; and (2) in listing THC as a Schedule I controlled substance, it carved out an exception which permits THC in hemp in concentrations not to exceed 0.3 % on a dry weight basis. The bottom line is that hemp plants with very low concentrations of THC are now legal to grow and sell so long as the business is following all other cannabis related regulations.

Many have taken the 2018 Farm Bill's amendments to the Controlled Substances Act, 21 USC § 801, *et. seq.*, to mean that CBD is legal; however, the answer is not so simple. The 2018 Farm Bill simply did not declare that CBD is legal and not subject to regulation. Rather, the 2018 Farm Bill legalized low levels of THC in hemp plants.

CBD remains subject to regulation by the FDA. Specifically, the 2018 Farm Bill:

explicitly preserved [the] FDA's authority to regulate products containing cannabis or cannabis-derived compounds under the [Food, Drug and Cosmetic Act] and section 351 of the Public Health Service Act (PHS Act). FDA treats products containing cannabis or cannabis-derived compounds as it does any other FDA-regulated products — meaning they're subject to the same authorities and requirements as FDA-regulated products containing any other substance. This is true regardless of whether the cannabis or cannabis-derived compounds are classified as hemp under the 2018 Farm Bill.

Because cannabis derived compounds like CBD are, for the first time since the Controlled Substances Act, being added to dietary supplements, food products, salves, even makeup, these products fall under the authority of the FDA. The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. This means the FDA regulates, foods, drugs, biologics like vaccines, medical devices, electronic products that give off radiation like microwaves, cosmetics, veterinary products, and tobacco products. It is clear the FDA intends to regulate CBD. The FDA has already held public hearings to obtain scientific data and information about the safety, manufacturing, product quality, marketing, labeling, and sale of products containing cannabis or cannabis derived compound like CBD.

While we await the results of the public comment period, the FDA has continued to evidence its intent to regulate CBD products. On July 22 of this year, the FDA sent a warning letter to Curaleaf Inc., stating that Curaleaf's CBD products were "misbranded drugs," in violation of the Food, Drug and Cosmetic Act. Curaleaf is a publicly traded company that cultivates, processes and sells medical cannabis. The FDA's warning letter to Curaleaf stated it was "illegally selling unapproved products containing cannabidiol (CBD) online with unsubstantiated claims that the products treat cancer, Alzheimer's disease, opioid withdrawal, pain and pet anxiety, among other conditions or diseases."

Curaleaf has challenged the FDA's warning letter, nonetheless, Dr. Ned Sharpless, acting FDA Commissioner, has stated:

Selling unapproved products with unsubstantiated therapeutic claims -- such as claims that CBD products can treat serious diseases and conditions -- can put patients and consumers at risk by leading them to put off important medical care. Additionally, there are many unanswered questions about the science, safety, effectiveness and quality of unapproved products containing CBD.

While many are eager to take advantage of the US's booming CBD market, as evident by the FDA's warning letter, businesses should use caution when selling CBD products and making efficacy claims as the FDA continues to analyze how it intends to regulate CBD.

[McCusker Anselmi Rosen & Carvelli P.C.](#) (MARC) provides legal counseling in New Jersey and New York. If you have a question regarding CBD law-related issues, call or write our attorneys directly at 973-635-6300 or 212-308-0070 and ask for [Allison Zsamba](#) (azsamba@marc.law) or [Bruce Goldstein](#) (bgoldstein@marc.law).